40 Old Lancaster Road Unit 615

Merion Station, Pennsylvania 19066

December 17, 2021

David Jokelson
Jokelson Law Group P.C.
230 S. Broad Street 10th Floor
Philadelphia, PA 19102

RE: Sipp-Lipscomb, et al v. Einstein Physicians Pennypack Pediatrics, et al

Dear Mr. Jokelson:

Thank you for consulting me in this matter concerning a two-year old male named Andres Gardin who presented with left scrotal pain and swelling. As you have requested, I have reviewed the records and ultrasound examinations performed at St. Christopher's Hospital for Children on 7/14/2019 at 3:49 AM and then again at 4:23 PM. I have also reviewed the Preliminary Report by Teleradiology Solutions and the Official (Final) Reports by Dr. Higgins. The following opinion is based on this material.

The initial ultrasound examination is not entirely satisfactory due to motion artifact nevertheless, it reveals a normal right testicle in the inguinal canal which is indeed also normal in size, shape and echotexture.

Examination of the left hemi-scrotum reveals a mildly enlarged left testicle (almost twice the size of the right) with a heterogeneous (mottled) echotexture surrounded by a small amount of fluid. There is also considerable superficial soft tissue swelling. While the color Doppler images show variably increased flow around the left testicle, there is no reliably demonstrated Doppler blood flow signal within the testicle itself. I therefore strongly disagree with the interpretation rendered by Dr. Kalyanpur of Teleradiology Solutions which described "normal echogenicity and Doppler flow signal" of the left testicle and stated in the Impression that there is "No evidence of testicular torsion." I do not believe that the Teleradiology Solutions report is correct and I do not believe that it meets the standard of care under the described circumstances.

The Tech Comments uploaded by the ultrasound technologist to Teleradiology Solutions at the time the Preliminary Report was ordered and requisitioned at 4:40 AM EDT state:

> "***EXTREMELY LIMITED STUDY, PT INCONSOLABLE/SCREAMING/CONSTANT MOTION - RT TESTIS WNL WITHIN ING CANAL, FLOW IMAGING LIMITED BUT VISUALIZED -LT**

TESTIS FLOW IMAGING LIMITED BUT SEEN, SIGNIFICANT INCREASE OF FLOW VISUALIZED IN AREA OF LT EPI *SPOKE TO ED ABOUT LIMITED RESULTS, WERE COMFORTABLE AND CHOSE NOT TO MEDICATE PT"[1]

The decision to discharge the patient seems to be based significantly on the comments made by the ultrasound technologist as documented in the Emergency note:

"U/S of poor quality, however, U/S tech reported good flow to both testicles during exam."

And further documented:

"07/24/2019 04:25 Spoke to US tech re pt. She said that while it was difficult to examine the pt 2/2[sic due to] the pt moving during the US she is confident there is good flow in both testicles. She reports she saw evidence of epididymitis on the left side."

This erroneous impression was subsequently reiterated by the Teleradiology Solutions report.

In a subsequent Quality Assurance Report which I reviewed it states:

> "The waveforms in the left testis are not real- they are related to motion. The echotexture of the testis is abnormal. The surrounding hyperemia is reactive to testicular torsion. The patient was rescanned the next morning- found to have torsion. This is a hard case b/c the patient was moving. As per the technologist, the ED would not sedate. The tech was counseled about this case."

These comments were reviewed by the Teleradiology attending who responded:

> **"Response:**
> Agree in retrospect, I was misled by Doppler signal in the testis and the limitations of the study.
> **Changes in Management/Outcome::**
> Presume surgical evaluation.
> **Modification in Reading Pattern If Any::**
> In technically suboptimal studies, exercise caution in waveform analysis."

In my opinion, given the absence of an official (final) report, the urgent need for an accurate interpretation, and the notations that the examination was "markedly" and "significantly" "limited" and "poor," the ultrasound examination should have either been repeated, and/or a surgical evaluation recommended, and/or the patient kept in the ER until the regular Pediatric Radiology attending was available to review the Ultrasound examination (assuming this could be accomplished in an expedited manner). Although the regular Pediatric Radiology attending

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[1] In the version of the Tech Comments produced by St. Christopher's Hospital for Children, the final comment—indicating the ED decided from the information provided by the tech without input from the teleradiologist that they were "comfortable" not sedating the patient and repeating the ultrasound—is omitted. However, following a quality assurance review, Dr. Erica Poletto, the Interim Radiology Department Chief, confirmed in a Quality Assurance Report that "As per technologist, the ED would not sedate. The tech was counseled about this case."

subsequently reviewed the ultrasound examination, this happened several hours later. But by then the patient had been discharged and it took hours to contact the family and bring the patient back.

Therefore, I believe that the ER and Urology staff were misled by the comments of the Ultrasound tech as well as the report of Teleradiology Solutions which led to the decision to discharge the patient from the ER and thus prolonged the time until the correct diagnosis could be properly established.

I hope that my comments will be helpful to you as you proceed with further legal action in this matter. All of my opinions are stated to a reasonable degree of medical certainty. Please do not hesitate to contact me as needed.

With best regards,

Richard I. Markowitz, MD

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August 31, 2021

To: David E. Jokelson, Esquire
Jokelson Law Group, P.C.
230 South Broad Street, 10th Fl.
Philadelphia, PA19102

Re: [redacted] (a minor)
D.O.B. 04/18/2017

Dear Mr. Jokelson,

I have reviewed the records of this case and in particular I have reviewed the following:

a) Medical Records from St. Christopher's Hospital for Children (including operative report of 7/24/2019);
b) Medical Records from Urology for Children;
c) Medical Records from Pennypack Pediatrics; and
d) Plaintiff's second amended complaint.

Specifically, you have asked me to address what impact the loss of [redacted] left testicle (he underwent left orchiectomy on 7/24/2019 due to testicular torsion and right orchidopexy) may bear on his future male endocrine function and future fertility. Given that both testicles function as endocrine and reproductive organs, the loss of one testicle may result either in no impact or in partial impact or in a total compromise of his future reproductive capacity. It will be very important to assess Andres pubertal developmental milestones to detect any deviation from established charts. As far as his reproductive function is concerned, an accurate assessment would entail detailed evaluation of a complete semen analysis and a full panel of reproductive hormones after puberty has occurred.

Nonetheless, [redacted] does face a potential increased risk of future infertility due to the loss of his left testis secondary to torsion, and the observation on ultrasound that his right testis was located close to the inguinal canal and required orchidopexy at the same time of the left orchiectomy. The magnitude of this risk can be more precisely assessed after the pubertal development as stated earlier in the report.

All opinions are offered within a reasonable degree of medical certainty, and I reserve the right to prepare supplemental reports.

Sincerely,

Pasquale Patrizio, MD, MBE, HCLD, FACOG
Professor, Obstetrics, Gynecology and Reproductive Sciences
Director, Yale Fertility Center

Daniel Rauch, M.D., F.A.A.P.
General Pediatrics and Pediatrics Hospital Medicine
25 Piedmont St, #3
Boston, MA 02116

December 18, 2021

David E. Jokelson, Esquire
Jokelson Law Group, P.C.
230 S. Broad Street, 10th floor
Philadelphia, PA 19102

RE: [redacted]

Dear Mr. Jokelson,

At your request, I have reviewed the medical records and materials that pertain to the care and treatment of [redacted] as provided by your office, including the chart from St. Christopher's Hospital for Children, records from Pennypack Pediatrics, and the reports by Dr. Markowitz, Dr. Casale, and Dr. Patrizio.

My opinions are limited to the information provided. If additional records or information become available, I ask that you provide such to me and I reserve the right to supplement and/or amend the opinions expressed herein.

The facts of the case are well known to you. [redacted] was a previously well 2 year old boy who woke up on July 23, 2019 with acute onset of testicular pain and swelling per his mother. By her report, as recorded in the history taken the following day at St. Christopher's, "she called the pediatrician's office and was advised that the swelling could be 2/2 to fluid accumulation and that she should observe the pt to see if the swelling resolved with time." Although Pennypack Pediatrics has no report of the call, records produced by T-Mobile confirm that an outgoing call was placed from the mother's mobile phone to Pennypack at 3:47 p.m. for a duration of 2 minutes, 41 seconds. There is also no record of any follow-up call by Pennypack to the family to check-in on Andres and his symptoms. The pain and swelling did get worse that night and she brought Andres to St. Christopher's where he was eventually diagnosed with testicular torsion and ultimately brought to the operating room on July 24, 2019. Unfortunately, his left testicle was not salvageable and needed to be removed. He tolerated the procedure well but now has only one testicle. He will need to wear a protective cup for participating in activities that may lead to genital trauma such as contact sports.

Pennypack Pediatrics failed to meet the standard of care by not recommending that Andres be brought to immediate medical attention for evaluation. In a child without any prior history of scrotal or groin problems, such as Andres, the most important consideration for acute onset of testicular pain and/or scrotal swelling is the possibility of

testicular torsion because there is a limited time frame to intervene before the testicle is lost due to lack of blood flow.[1] The presence of an acute scrotum under these circumstances constitutes a well-recognized urological emergency. Although there are other causes of testicular pain and scrotal swelling and torsion is relatively uncommon in young children the priority is still to evaluate for torsion because of the potential dire consequence. Additionally, the evaluation generally is a non-invasive ultrasound exam that poses no risk to the child. The failure to have [redacted] be seen immediately led to delay in diagnosis and loss of his testicle. Pennypack Pediatrics additionally failed to meet the standard of care by having no record of the call or advice given.

All my opinions are to a reasonable degree of medical certainty.

If you need any additional information, please to do not hesitate to contact me.

Sincerely,

Daniel Rauch, M.D., F.A.A.P.

[1] As for the for the duration of this limited time frame, I defer to the opinions expressed by Dr. Casale, a pediatric urologist.

Pasquale Casale, MD, MHA

615 E. Princeton Street, Suite 310

Orlando, Florida 32803

December 14, 2021

David Jokelson, Esquire
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Philadelphia, Pa. 19102
(215) 735-7556

RE: Sipp-Lipscomb v. Pennypack Pediatrics, et al.

Dear Mr. Jokelson:

In my capacity as a physician since 1996, and specifically as a Board Certified Urologist with a Subspecialty Certificate of Added Qualification from the American Board of Urology for Pediatric Urology, you have requested that I address issues concerning liability and damages for loss of a testis due to testicular torsion. The main concerns of parents and patients who present with loss of a testis are, in no particular order, hormone levels, infertility, disfigurement, psycho-social development, and activity in sports. As a constituent part of my training and practice, I have diagnosed, treated, and operated on many patients for testicular torsions and have provided on-call services to several hospital emergency departments including at the Children's Hospital of Philadelphia, New York-Presbyterian/Morgan Stanley Children's Hospital, and AdventHealth Orlando. The basis of my opinions is derived from my extensive experience with children and young adults who have lost a testis from testicular torsion, as well as reviewing documents with the following facts pertinent to the case:

On July 23, 2019, the mother of [redacted], a 2 year old boy, called the pediatrician's office, Pennypack Pediatrics (Pennypack). Although Pennypack claims that it cannot locate any record or note of the call, mother's cell phone records show a 2 minute 41 second call to Pennypack at 3:47 PM. Later records from St. Christopher's Hospital for Children (SCHC) confirm that the mother had called Pennypack with complaints of scrotal pain and swelling. They were told according to the mother that he should just be observed at home. There is no record of any follow up by Pennypack with the family on July 23 or 24, 2019.

On July 24, 2019, at about 3:08 AM EDT, this 2 year old boy presented to the SCHC Emergency Room (ER) for scrotal pain, swelling, and redness. The History of Present Illness recorded in the ED Note-Physician (ED Note) electronically signed by Erin Hassel, MD (a Graduate Medical Trainee in the first

month of her first rotation during the internship year of her residency in Emergency Medicine) and the attending ER physician, Pramath Nath, MD, confirms that:

> The patient presents with testicular pain and scrotal swelling. The onset was 12 hours ago. The course/duration of symptoms is fluctuating in intensity. Type of injury: none. Location: Left testicle. Radiating pain: none. The character of symptoms is sharp. The exacerbating factor is palpation. The relieving factor is lying down. Risk factors consist of none. Prior episodes: none. Therapy today: none. Associated symptoms: none.
>
> Previously healthy 2 y/o M presents with left testicular pain/swelling that began ~1500 yesterday. Mom reports that after the pt woke up from a nap he was walking with his legs farther apart than usual while leaning forward. She examined him and noted that his left testicle was swollen and tender to the touch. She reports that she called the pediatrician's office and was advised that the swelling could be 2/2 to fluid accumulation and that she should observe the pt to see if the swelling resolved with time. The swelling improved during the evening and then worsened at night. Mom reports the swelling is currently at its worst. Also endorses redness and tenderness of the left testicle. Mom denies f/c, n/v, dysuria, hematuria. Denies trauma to testicles. Denies any therapy today. Denies h/o similar symptoms.

At 3:49 AM EDT, a Scrotal Ultrasound was performed by an ultrasound technologist, Haley Bartkus. Before a Preliminary (unofficial) Report of the Ultrasound was ordered and requisitioned at 4:40 AM EDT from Teleradiology Solutions (TS) or any informal interpretation or "wet" read was obtained from any radiologist, the ED Note recorded at 4:25 AM EDT that, "Spoke to US tech re pt. She said that while it was difficult to examine the pt 2/2 to the pt moving during US she is confident there is good blood flow in both testicles. She reports she saw evidence of epidymitis on the left side." At 4:34 AM EDT, the ED Note recorded (again before any involvement with TS or any of its interpreting teleradiologists) that, "Consulted urology [Eric Cho, MD, a Graduate Medical Trainee in Urology completing the first month of his Pediatric rotation] re pt. Relayed that US tech was NOT concerned for torsion, saw signs of epididymitis (LEFT). Informed urology of plan to treat pt with motrin Q8 for 5 days and have f/u with pediatrics. Urologist reported that he would view images and call back."

Contemporaneous with the order and requisition of the Preliminary (unofficial) Report of the Ultrasound at 4:40 AM EDT from TS, Ms. Bartkus uploaded her Tech Comments to TS through its online portal. The version of Ms. Bartkus' Tech Comments produced by TS states that:

> ***EXTREMELY LIMITED STUDY, PT INCONSOLABLE/SCREAMING/CONSTANT MOTION**
>
> **-RT TESTIS WNL WITHIN ING CANAL, FLOW IMAGING LIMITED BUT VISUALIZED**
>
> **-LT TESTIS FLOW IMAGING LIMITED BUT SEEN, SIGNIFICANT INCREASE OF FLOW VISUALIZED IN AREA OF LT EPI**
>
> ***SPOKE TO ED ABOUT LIMITED RESULTS, WERE COMFORTABLE AND CHOSE NOT TO MEDICATE PT**

The fourth comment—that the ED had declined to order sedation because they were "comfortable" with the "extremely limited study" results reported by Ms. Bartkus without the input of any interpreting radiologist—is omitted from the version of the Tech Comments produced by SCHC. However, Ms. Bartkus' fourth comment is confirmed by Erica Poletto, MD (SCHC's Interim Radiology Department

Chief) in a later Quality Assurance Report where she provides that, "As per the technologist, the ED would not sedate. The tech was counseled about this case."

The SCHC Chart Access Log identifies that at 5:01 AM EDT, Dr. Cho accessed the patient's chart, and the ED Note records at 5:32 AM EDT that, "Spoke to urology. Urologist reported that he was not confident in the results of the US. He is coming in to evaluate the pt." At 5:33 AM EDT, a Preliminary (unofficial) Report on the Scrotal Ultrasound was electronically signed by Teleradiologist Arjun Kalyanpur, MD, and then transmitted to SCHC by fax at 5:35 AM EDT. This Preliminary (unofficial) Report reports findings that include "Significantly limited evaluation due to noncooperative patient," as well as that both the left and right testicle "demonstrate normal echogenicity and Doppler flow signal." The impressions include "1. Markedly limited evaluation as described. 2. No evidence of testicular torsion on this limited evaluation. 3. Increased flow to the left epididymis. In the appropriate clinical setting, epididymitis cannot be excluded. Recommend clinical correlation and follow."

During the initial ER visit there was a Urology Consult Note at 6:00 AM EDT electronically signed by Dr. Cho at 6:14 AM EDT and by the attending urologist, Charles Concodora, MD, at 8:20 PM EDT on July 28, 2019. (The SCHC Chart Access Log identifies that Dr. Concodora first accessed the patient's chart four days later at 8:21:21 PM EDT on July 28, 2019.). Dr. Cho reports that "On U/S bilateral testicles demonstrate normal flow," but does not mention the limitations of the study or that "he was not confident in the results of the US." Additionally, Dr. Cho notes a history of "Never complained of pain on that side," even though the ER physician reports a history of "testicular pain and scrotal swelling" in the History of Present Illness in the ED Note. Dr. Cho also notes GU was "Normal," however the ER physician noted "cremaster reflex absent b/l (bilaterally)." Dr. Cho noted his assessment of "Likely left appendix testicular torsion with concurrent communicating hydrocele," and the plan was for follow-up and pain treatment with no urologic intervention needed "as appendix torsion is self resolving." As noted, this was discussed with Dr. Concodora who concurred, noting that he did not personally examine the patient or review the US images, and that "There was no report of pain/discomfort, except during physical exam." Dr. Concodora also reported that "Per the resident, the ultrasound was officially reported as normal with normal testicular flow bilaterally," even though no official report was generated until after the patient was discharged, and the Preliminary (unofficial) Report noted significant and material limitations. Dr. Concodora thus concluded that "Given the constellation of findings, including the young age of the patient, testicular torsion was unlikely, and the patient likely has an appendix testis torsion or communicating hydrocele. No acute surgical intervention is necessary for either, and can be followed up as an outpatient."

The ED Note records in an untimed section Medical Decision Making:

> **Differential Diagnosis**: Testicular torsion, epididymitis, inguinal hernia, orchitis
>
> **Rationale**: Left testicle erythematous, warm, swollen. No h/o of fever, parotitis, n/v, dysuria, hematuria. U/S of poor quality, however, U/S tech reported good blood flow to both testicles during exam. Imaging did reveal swelling consistent with epididymitis.
>
> **Documents reviewed**: None available.

The ED Note records at 6:32 AM EDT, "Spoke with EM attending re urology recommendations. Agreed with Q8 motrin for 5 days. Want to see in urology clinic in 2 weeks." The ER physicians assigned a final diagnosis of "Left testicular pain," and the patient was discharged with educational materials for epididymitis and instructions to follow up with the Pediatrician in 3-5 days and with a Urologist in 10-14 days. The ED Note does not record that the ER physicians reviewed the Preliminary (unofficial) Report of the Scrotal Ultrasound electronically signed by Dr. Kalyanpur.

Hours after discharge at 9:31:16 AM EDT, the SCHC Chart Access Log identifies that the onsite radiologist, Timothy Higgins, MD, accessed the patient's chart. In the Final (official) Report of the Scrotal Ultrasound that Dr. Higgins later prepared, he reported findings that "The left testicle is slightly heterogeneous in echogenicity" and "Normal smooth arterial and venous waveforms are not documented," and impressions that:

1. Definitive blood flow with normal-appearing waveforms is not documented in either testis, which may be technical or secondary to motion.

2. There is hyperemia surrounding the left testicle and involving the epididymis, and the left testicle demonstrates a heterogeneous echogenicity. Although a preliminary report was provided by teleradiology indicating no evidence of testicular torsion on this limited evaluation, repeat ultrasound with color and spectral Doppler imaging is recommended to exclude testicular torsion and document normal blood flow in the testes.

3. Revised findings were called to the nurse practitioner Stephanie in the emergency room at the time of over read by Dr. Higgins at 10:00 AM.

A Rad-Lab Results Addendum *ED by Stephanie Curtis, CRNP, noted that at "10:05 received phone call from Dr. Tim Riggs Radiology who reviewed patients nighthawk read of the US completed while seen in the ED o/n. Radiologist recommends having repeat scrotum US completed to ensure blood flow to L testes given the limited exam from overnight." It was also noted at "10:15 Spoke with Urology via RN as they were in an OR case given their clinical assessment of patient while in the ED who states that repeat US is suggested given concern." However, at this point the patient had left the ER.

The patient returned to the ER, and a Urology Consult Note at 5:06 PM EDT electronically signed by Dr. Cho noted that "2 year old male with left testicular torsion. Bounce back to the ED after U/S read from earlier today was amended from a normal testicular u/s to an abnormal one. On Repeat u/s this afternoon, there is no flow seen on the left testicle. His physical exam has not changed from the morning. There is still enlargement of the left testicle which was thought to be a communicating hydrocele from this morning." It was only at this point that the definitive diagnosis of testicular torsion was made, and the left testis had to be removed. It was not salvageable.

In a Quality Assurance Report (QAR) finalized by August 19, 2019, Dr. Poletto provided that:

> **QA Point**: The waveforms in the left testis are not real- they are related to motion. The echotexture of the testis is abnormal. The surrounding hyperemia is reactive to testicular torsion. The patient was rescanned the next morning- found to have torsion. This is a hard case b/c the patient was moving. As per the technologist, the ED would not sedate. The tech was counseled about this case.

Dr. Kalyanpur reviewed the QAR which further states:

> **Response:**
> Agree in retrospect. I was misled by Doppler signal in the testis and the limitations of the study.
>
> **Changes in Management/Outcome:**
> Presume surgical evaluation.
>
> **Modification in Reading Pattern If Any:**

In technically suboptimal studies, exercise caution in waveform analysis.

It is my opinion with a reasonable degree of medical certainty that there were many events that fell below the standard of care. These events include without any order of preference:

1. The pediatrician's office should have instructed the mother to take the child immediately to the ER for evaluation of scrotal pain. Scrotal pain should never be observed until proven that it is safe to do so.

2. An ultrasound technologist gave a preliminary report when it is out of the scope of practice for a nonphysician to do so.

3. Dr. Hasssel and Dr. Nath elected, based upon the report of the ultrasound technologist and without the input of a Radiologist, not to sedate the patient to repeat the Ultrasound.

4. Although Dr. Hassel and Dr. Nath reported that the patient was presenting with a history of acute scrotal pain and swelling, that the Ultrasound was "of poor quality," and that Dr. Cho "reported that he was not confident in the results of the US," and the Preliminary Report (which the chart does not indicate was seen by the ER physicians) states that the ultrasound was "materially" and "significantly limited," they ruled out a testicular torsion and the patient was prematurely discharged without a repeat ultrasound, a Final (official) Report of the Ultrasound, and/or a surgical evaluation.

5. Dr. Cho misreported to Dr. Concodora that "there was no report of pain/discomfort." Dr. Cho also misinformed Dr. Concodora that the Ultrasound was "officially reported as normal with normal testicular flow bilaterally" without advising that the ultrasound was "of poor quality" and the study was unofficially reported to be "materially" and "significantly limited."[1]

6. Dr. Concodora should have reviewed the images himself as every Pediatric Urologist is trained to perform and interpret Ultrasounds. If Dr. Concodora has ever performed an Ultrasound in the office himself or by one of his staff, he would render an interpretation. As Pediatric Urologists, we would easily recognize changes in the testes consistent with torsion that might be misinterpreted otherwise.

7. Dr. Concodora is also aware as a Pediatric Urologist that testicular torsion is a diagnosis of exclusion at the time of surgery. Therefore, if an Ultrasound is suboptimal then time is of the essence. A patient, regardless of age, should be surgically explored. Testicular torsion is more common in adolescents and young adults, but can happen at any age. We are taught this during our residency and fellowship training. If an Ultrasound is inconclusive or limited, it cannot be trusted. Also, the likelihood of epididymitis in a 2 year old boy who does not have dysfunctional voiding, obstructive urethral uropathy, a history of intermittent catheterization, sexual abuse, and/or a viral illness such as mumps with a normal urine analysis is extremely unlikely. In this setting, the images do not show epididymitis but show increased peripheral flow consistent with a torsion. If Dr. Concodora would have viewed the images himself, it is reasonable to state that he would have noted this as it is standard practice for Pediatric Urologists to note this finding.

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[1] A Final Report is the official interpretation of an imaging examination or procedure by an interpreting physician and constitutes the definitive documentation of the results. It is understood that a Preliminary Report—an unofficial interpretation that may precede a Final Report—very likely will contain limited or incomplete information and should not be expected to contain all the information subsequently found in the Final Report.

Acute scrotal pain is a urological emergency requiring prompt assessment. The differential diagnosis includes testicular torsion—a twisting of the spermatic cord and its contents—which is a major concern because it requires immediate surgical intervention. Accordingly, in the presence of an acute scrotum, as reported by the mother to Pennypack and noted in the SCHC chart, it imperative to rule out testicular torsion emergently. Because spermatic cord torsion is a potentially reversible condition when diagnosed and treated early, the emphasis should be on prompt evaluation of children who present with an acute scrotum. Prompt recognition and treatment are necessary for testicular salvage, and torsion must be excluded in all patients who present with acute scrotum. Delay in treatment may necessitate orchiectomy and be associated with decreased fertility. The prompt identification of a testicular torsion and institution of therapy are crucial as the therapeutic window for testicular salvage closes over time. Accordingly, the standard of care requires a high index of suspicion which none of the providers employed in this case. Instead, the patient's urological emergency was effectively ignored by Pennypack and the patient was later prematurely discharged from SCHC without stabilization of a known urological emergency and without the regular screening procedures which in this case included a repeat scrotal ultrasound or surgical evaluation.

When torsion causes infarction and the testis dies, there are physiologic changes that occur. Even though the pituitary hormones that regulate the testes increase and stimulate the remaining healthy testis, the long-term outcome is known that in about 1/3 of cases a man's sperm count is below normal after torsion, potentially causing him difficulty in fathering a child.

Hormone levels are definitely diminished after acute loss of a testis, but in the long term even though these hormone levels return to normal, the effect post puberty of acute low levels in the prepubescent child is not always well defined at this age, and may result in and does place the patient at an increased risk for conditions such as loss of muscle strength, osteoporosis, loss of sex drive, erectile dysfunction/inability to achieve or maintain erection, hot flashes, weight gain, depression or low mood, and increased risk of cardiovascular disease.

It is also imperative that the boy who has already lost one testis always wear a protective cup when playing contact sports. He and his family must always remain attentive throughout the boy's lifetime that it is imperative to seek immediate medical attention in the event of any discomfort, pain or anything out of the ordinary with the scrotum or remaining testis.

Undisputable is that he will have a deformity in the scrotum from missing a testis, and it is readily apparent that he will have only one testis. Although Pediatric Urologists cannot make psychological or psychiatric diagnoses, we have the knowledge and experience to refer patients when we are concerned for psychological issues arising from the impacted genitourinary system such as ambiguous genitalia, types of behavioral voiding dysfunction, malignancy, renal transplant patient, and those boys who have issues with the loss of a testis. The psychological impact will be there, however the depth will only be known over time.

If he elects to have a prosthesis put in to alleviate this deformity, it comes with a financial and potential health cost. However, the undertaking of such a surgery should not be taken lightly. There are pros and cons to placing one. They are as follows:
The benefits of getting a testicular prosthesis include:
- From the outside, the scrotum will appear the same or at least close as before loss of the testis.
- Most patients who have a testicle implant say it makes them feel better about themselves.
- It can be removed if there are any problems.
- The implant is available in sizes from extra small to large, so it can be matched to the other

testicle.
• Surgery to place the testicle implant can be done in an outpatient setting, and the patient can usually go home the same day. Recovery is typically two weeks.

The cons of getting a testicular prosthesis include:
• While the outside appearance may be the same, the actual feel of the current, saline-filled or solid silicone implant is usually harder and less malleable than a natural testicle.
• You may not like how the implant looks. In one study, 23 percent of patients said they were dissatisfied with the testicle implant's position or shape.
• The testicle implant is merely cosmetic, so it won't produce sperm or testosterone.
• If a developing adolescent receives an implant, he may need to have it replaced with a larger prosthesis at some point, so another surgery will be needed.
• There are complications. The implant could erode through the skin, move around, hurt, swell, bleed, or scar on both the outside and inside. All of these complications would require further surgery.
• The life span of the prosthesis is typically 10 to 15 years requiring replacement even if there are no complications. Accordingly, if he elects for a prosthesis, this patient will have multiple (likely four or more) over his life span. Today's out-of-pocket cost for a testicle implant is $12,000.
• As with any surgery, there are risks associated with anesthesia, which should be fully discussed beforehand.
• You may or may not be reimbursed by your insurer for the surgery.

It is with a reasonable degree of medical certainty that there was a breach in duty as the physicians should have recognized and commented on the changes in the testicle which would have led to surgical intervention with a probability of saving the testis. In the first 6 hours of torsion, 95% of testes are salvageable, 80% at 12 hours, and even 24 hours later there is still a possibility albeit low at 40%. These data points are well documented in the literature which is why time is of the essence in testicular torsion cases. I do not believe the standard of care was met in this case. I also believe as outlined in the possible future risks above that this child will suffer in the future from the incident with damages being potential infertility; change in appearance; possible psychological impact that can affect him socially and sexually; and acute hormonal changes from which the overall (and potentially very significant) impact is never known in preadolescent boys until after they mature, and can be properly evaluated.

I thank you for seeking my opinion in this matter. I reserve the right to add or amend my opinions should further information come forth.

Respectfully submitted,

Pasquale Casale, MD, MHA

Pasquale Casale, MD, MHA

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Orlando, Florida 32803

March 3, 2022

David Jokelson, Esquire
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Philadelphia, Pa. 19102
(215) 735-7556

RE: Gardin v. Pennypack Pediatrics, et al response to Dr. Berger

Dear Mr. Jokelson:

I am writing a response to the report by Scott Berger, MD, PhD. I respectfully disagree with statements made by Dr Berger pertaining to my report.

1. Dr. Berger states that my report is erroneous in the time survival of testes. He states that the "vast majority" of the literature shows that testes salvaged beyond 8 to 12 hours from the onset of symptoms all atrophy over time. This statement is completely false from both a literature standpoint and clinical experience. The literature shows there is survival without atrophy even in cases that surpass 24 hours. The salvage rate is lower than in the first 6 hours, but it is not a zero percent over the long haul. My experience shows, and the literature supports, that even with a finding of heterogeneity on ultrasound, the long term survival is much higher than suggested by Dr. Berger, a radiologist. He obviously has never followed children past the time of the ultrasound review. I understand he might see children with atrophy in the long run with long standing torsion, but I believe he would not see the survivors as we don't always get ultrasounds when those children are doing well clinically.

2. Dr. Berger also wrongfully interpreted my manuscript on flaps for torsion. We showed three children with changes on ultrasound of heterogeneity even in what most consider the best window we have which is within 6 hours. My manuscript shows that these changes are not always necrosis, but can be edema with high compartment pressures which appears as heterogeneity on ultrasound. They were not "non-salvageable", but prolonged torsion might have caused further damage so prompt intervention is warranted despite timing and/or ultrasound findings. I state this because you never fully know how the testicle has been acting in regards to how the torsion might be presenting. For example, you can have an intermittent torsion for a day which becomes a complete torsion at any point with edema and these findings on ultrasound. Testicular torsion is considered a diagnosis made at surgery. Therefore even though exam and ultrasound are helpful, and both help surgeons make a decision, nonetheless, they should never be relied on in their entirety when it comes to testicular torsion. Testicular torsion is only conclusively diagnosed at the time of surgery. It is standard of care to perform surgery and find no torsion in the acute

scrotal pain patient, but it is not the standard of care to miss torsion in an acute scrotal case where the surgeon decided not to operate.

3. My third point is the heterogeneity on ultrasound. As I stated in point number 2 above, heterogeneity on ultrasound is not definitive for necrosis. Necrosis is a diagnosis that can only be made by a pathologist on a specimen. Heterogeneity on an ultrasound during the evaluation for torsion can be a sign of necrosis, or edema, or both. However, the viability of the testis can only be ascertained by surgery. Ultrasound is never the final answer to testicular salvage. We as pediatric urologists have all saved a testis that is more than 6 hours out from symptoms. In my own experience, I have saved testes after six hours, and one even as far out as 5 days from the onset of symptoms, albeit uncommon. Therefore, you cannot predict what is salvageable 100% of the time radiologically, but you can predict what is salvageable 100% at surgery.
4. In regards to atrophy, they don't all atrophy. It is simply false to state that no testes that are torsed for more than 12 hours survive the long term. What this statement by Dr. Berger shows is that Dr. Berger, as a radiologist, just does not have the clinical experience of a pediatric urologist who follows these children.

I still hold that it is with a reasonable degree of medical certainty that there was a breach in duty as the physicians should have recognized and commented on the changes in the testicle which would have led to surgical intervention with a probability of saving the testis. In the first 6 hours of torsion, 95% of testes are salvageable, 80% at 12 hours, and even 24 hours later there is still a possibility albeit low at 40%. See e.g., Mellick LB, Sinex JE, Gibson RW, Mears K. A Systematic Review of Testicle Survival Time After a Torsion Event. *Pediatr Emerg Care*. 2019;35(12):821-825. (Comparing survivability at time intervals from 30 studies with 2116 testicular torsion patients.).[1] These data points are well documented in the literature which is why time is of the essence in testicular torsion cases, and radiological interpretation cannot not be relied upon alone. I do not believe the standard of care was met in this case. I also believe the possible future risks above that this child can suffer in the future from the incident with damages from a change in appearance; possible psychological impact that can affect him socially and sexually; and acute hormonal changes which the overall impact is never known in preadolescent boys until after they mature, and can be properly evaluated.

I thank you for seeking my opinion in this matter. I reserve the right to add or amend my opinions should further information come forth.

Respectfully submitted,

Pasquale Casale, MD, MHA

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[1] Of testicles viable at the time of surgery beyond 12 hours, Mellick also references an earlier large-scale study and 2 meta-analyses showing much lower rates of atrophy than suggested by Dr. Berger:

> in a large study of 537 TT patients by Anderson and Williamson,[ ] atrophy in testicles viable at the time of operation was 0% at 0 to 6 hours, 1% at 7 to 12 hours, 15.8% at 13 to 18 hours, 35.7% at 19 to 24 hours, 81.3% at 25 to 48 hours, and 66.7% in the small number surviving greater than 48 hours. Visser and Heyns also graphically reported on atrophy data from the 2 meta-analyses reported previously. Atrophy was approximately 2% for surviving testicles surgically managed between 1 to 6 hours, 8% at 6 to 12 hours, just over 40% at 12 to 24 hours, and just under 80% at greater than 24 hours.

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March 2, 2022

To: David E. Jokelson, Esquire
Jokelson Law Group, P.C.
230 South Broad Street, 10d'Fl.
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Re: [redacted] (D.O.B. 04/18/2017)

Dear Mr. Jokelson,

I have reviewed the defense expert report authored by Scott B. Berger, M.D., PhD (Neuroradiologist) dated February 3, 2022, and I am submitting this report as supplemental to my original opinion dated Aug.31, 2021.

From his review of the case, Dr. Berger identifies (3:49 a.m. Color Doppler Scrotum Ultrasound of 7/24/2019 -Berger Report page. 4) that: "The right testicle is in the inguinal canal and is abnormally pear-shaped; it demonstrates normal internal echotexture with no mass, hydrocele or varicocele. *The possibility of right cryptorchidism is raised"*. Dr. Berger's preliminary impression concludes that "Asymmetry of testes: the right is smaller and situated in the inguinal canal – this could represent cryptorchidism. The left is larger, the significance of which is unclear". Of note, Dr. Berger finds that "The left testis and the left epididymis are both larger than the right. (*However, is the right testis abnormally small, or is the left testis abnormally large, or a combination of the two? My initial impression is that the right testis is abnormally small due to the fact that it is in the inguinal canal and pear shaped*.)"

Regarding the Color Doppler Scrotum Ultrasound, Dr. Berger again finds notes as preliminary impression (at 4.25 pm, pp. 5-6) "The right testis is unchanged. It remains in the inguinal canal and is of normal echotexture…. The left tests is unchanged in size [i.e. larger than the left]." Dr. Berger's preliminary impression concludes that "Small right testis with abnormal pear-shape, normal right testicular blood flow. This could represent cryptorchidism."

Specifically, I have been asked to address what impact the loss of Andres Gardin's left testicle (he underwent left orchiectomy on 7/24/2019 due to testicular torsion and a right orchidopexy) may bear on his future male endocrine function and future fertility. I had already raised a concern, in my original letter of 8/31/2021, that on ultrasound his right testis was noted as located close to the inguinal canal (thus requiring orchidopexy) at the same time of the left orchiectomy. Now, having read Dr. Berger's conclusions, that the

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child had a cryptorchid right testicle (right testis small and high in the inguinal canal) there is an increased risk for a possible impact on future fertility, after losing his left testicle to torsion and having a right cryptorchid testicle.

It will be very important to assess [redacted] pubertal developmental milestones to detect any deviation from established charts. As far as his reproductive function is concerned, an accurate assessment would entail detailed right testis evaluation and a complete semen analysis with a full panel of reproductive hormones after puberty has occurred.

All opinions are offered within a reasonable degree of medical certainty, and I reserve the right to prepare supplemental reports.

Regards,

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